TABLE 1

Summary of Significant Treatment-Related Toxicological Parameters in the Reproductive/ Developmental and General Toxicity Study of AZT/Clarithromycin

Body Weights

Treatment Regimen	Males	Females-**A**	Females-**B**
AZT Alone	no body weight change	decrease in body weight	no body weight change
Clarithromycin Alone	decrease in body weight	decrease in body weight	decrease in gestational body weight
AZT + Clarithromycin	decrease in body weight	decrease in body weight	decrease in gestational body weight

Clinical Pathology

Treatment Regimen	Males	Females-**A**	Females-**B**
AZT Alone	-mild decrease in RBC, HGB, and HCT -mild increase in MCV and RDW	-mild decrease in RBC, HGB, and HCT -mild increase in MCV and RDW	-mild increase in MCV and RDW
Clarithromycin Alone	-mild neutrophilia	-neutrophilia -reticulocytopenia -decreased MCV -leukocytosis -increase in BUN and creatinine -increase in ALP, ALT, AST, and bile acids	-reticulocytopenia -decreased MCV
AZT + Clarithromycin	-anemia -increased MCV in lower dose groups -decreased MCV in higher dose groups -reticulocytopenia -thrombocytosis -neutrophilia -lymphopenia -increased RDW -increase in ALP, ALT, AST, and bile acids	-anemia -increased MCV in lower dose groups -decreased MCV in higher dose groups -reticulocytopenia -thrombocytosis -neutrophilia -lymphopenia -increased RDW -increase in BUN and creatinine -increase in ALP, ALT, and bile acids	-increased MCV -increased RDW

TABLE 1 (Continued)

Summary of Significant Treatment-Related
Toxicological Parameters in the Reproductive/
Developmental and General Toxicity Study of AZT/Clarithromycin

Histopathology

Treatment Regimen	Males	Females-**A**
AZT Alone	Liver -hepatocellular cytoplasmic alteration (slight) Spleen -hematopoietic cell proliferation (slight); hemosiderosis (slight)	Liver -hepatocellular cytoplasmic alteration (slight) Spleen -hematopoietic cell proliferation (slight); hemosiderosis (slight)
Clarithromycin Alone	Liver -cytoplasmic alteration -hepatocyte necrosis -cytoplasmic vacuolization Spleen -red pulp atrophy -lymphoid follicle depletion Bone marrow -depletion Kidney -nephropathy Lymph nodes -depletion Thymus -atrophy Brain, choroid plexus -cytoplasmic vacuolization Heart -cytoplasmic vacuolization of valve -degeneration of atrium -necrosis of myocardium Glandular stomach -cystic degeneration Stomach -fungal infection Salivary gland -necrosis	Liver -cytoplasmic alteration -hepatocyte necrosis -cytoplasmic vacuolization Spleen -red pulp atrophy -lymphoid follicle depletion Bone marrow -depletion Kidney -nephropathy Lymph nodes -depletion Thymus -atrophy Brain, choroid plexus -cytoplasmic vacuolization Heart -cytoplasmic vacuolization of valve -degeneration of atrium -necrosis of myocardium Glandular stomach -cystic degeneration Stomach -fungal infection Salivary gland -necrosis

Note: Histopathological evaluations were performed only on gross lesions in Female-**B** mice.

TABLE 1 (Continued)

Summary of Significant Treatment-Related
Toxicological Parameters in the Reproductive/
Development and General Toxicity Study of AZT/Clarithromycin

Histopathology (Continued)

Treatment Regimen	Males	Females-**A**
AZT + Clarithromycin	Liver -cytoplasmic alteration -hepatocyte necrosis -cytoplasmic vacuolization Spleen -lymphoid follicle depletion -red pulp atrophy -hemosiderosis Bone marrow -depletion Kidney -nephropathy Lymph nodes -depletion Thymus -atrophy Brain, choroid plexus -cytoplasmic vacuolization Heart -cytoplasmic vacuolization of valve -degeneration of atrium -necrosis of myocardium Glandular stomach -cystic degeneration Stomach -fungal infection Salivary gland -necrosis	Liver -cytoplasmic alteration -hepatocyte necrosis -cytoplasmic vacuolization Spleen -lymphoid follicle depletion -red pulp atrophy -hemosiderosis Bone marrow -depletion Kidney -nephropathy Lymph nodes -depletion Thymus -atrophy Brain, choroid plexus -cytoplasmic vacuolization Heart -cytoplasmic vacuolization of valve -degeneration of atrium -necrosis of myocardium Glandular stomach -cystic degeneration Stomach -fungal infection Salivary gland -necrosis

Note: Histopathological evaluations were performed only on gross lesions in Female-**B** mice.

TABLE 1 (Continued)

Summary of Significant Treatment-Related
Toxicological Parameters in the Reproductive/
Developmental and General Toxicity Study of AZT/Clarithromycin

Reproductive/Developmental

Treatment Regimen	Females-**A** Fetuses	Females-**B** Pups
AZT Alone	-reduced live litter size -increased number of resorptions -slight decline in fetal weight per litter	-no adverse effects
Clarithromycin Alone	-reduced live litter size -no conceptuses delivered in high dose group -slight decline in total weight per litter	-decreased number of litters delivered in high dose groups -decreased litter size -decreased number of pups surviving to post natal day 4 -reduced pup weight/litter
AZT + Clarithromycin	-reduced live litter size -increased number of resorptions -no conceptuses delivered in highest combination groups -prominent decline in total weight per litter	-decreased incidence of pregnancy -decreased number of litters delivered in highest dose groups -decreased litter size -decreased number of pups surviving to postnatal day 4 -reduced pup weight/litter -increased duration of gestation